



# **Dermal Sensitization Quantitative Risk Assessment (QRA) For Fragrance Ingredients: IDEA QRA Workshop Outcome March 2013**

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**IDEA Workshop**  
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# QRA Refinement

- **Review current QRA model for dermal sensitization to better explain:**
  - **SAFs**
    - **Inter-individual variability**
    - **Matrix effects**
    - **Use effects**



# QRA Refinement

## ● Exposure

- New exposure data (Hall, 2011) should be considered.
- RIFM sponsored work to investigate the effects of aggregate dermal exposure. This must be incorporated into the methodology.
  - In order to incorporate dermal aggregate exposure, modification of the SAFs is needed



# QRA Refinement: SAFS

- **Transparency in assignment of SAFS**
- **Modify in order to include aggregate exposure**
- **Inter-individual variability**
  - **Is there a need to deviate from generally accepted uncertainty factors used in general toxicology?**
  - **Has compromised skin been adequately addressed?**



# QRA Refinement: SAFS

- **Product Matrix**

- **Has being overly conservative lead to confusion?**

- **Use Matrix**

- **Compromised Skin was included in this SAF; if accounted in the inter-individual variability, then must be sure that there is no “double accounting”**



# QRA Refinement

- **Communication – expand the dialogue with international dermatologists.**
- **Relationship between induction and elicitation thresholds**
  - **ROAT on eugenol in progress**
  - **ROAT on citral planned**



# QRA Refinement

- **Effectiveness of the QRA (discuss at May 2014 Workshop)**
  - **Prospective study designed with ESCA & IVDK**
- **Retail Consumer Products Only (discuss at May 2014 Workshop)**
  - **The method does not apply to occupational use of consumer products or consumer products that are covered by other regulations (e.g. medical devices, OTC drugs, drugs).**
  - **Occupational exposure to consumer products**



# Summary: Key Actions March 2013



- **Include aggregate exposure in the QRA**
  - **In order to incorporate dermal aggregate exposure, modification of the SAFs is needed**
- **Review supporting information for SAFs to explicitly include application to damaged skin**
- **Communication – expand the dialogue with international dermatologists**
- **Explore relationship between induction and elicitation thresholds**
- **Measure effectiveness of the QRA in limiting the induction of contact allergy**
- **Incorporate occupational exposure to consumer products**



# More Information



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